JACC Vol. 18, No. 1
July 1991:159–65

Results of Balloon Pulmonary Valvuloplasty as a Palliative Procedure In Tetralogy of Fallot

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Balloon pulmonary valvuloplasty was attempted in 67 patients with tetralogy of Fallot at a median age of 5 months (range 0.03 to 52 months) for relief of cyanosis. In three patients, the valve could not be crossed and an aortopulmonary shunt was performed. In 35 patients, follow-up angiography was performed 3 to 30 months (average 12) after valvuloplasty. In 24 of these 35 patients (group A), the stenosis had been adequately palliated by valvuloplasty; the other 11 patients (group B) had required an aortopulmonary shunt 1 month (range 0 to 3 months) after valvuloplasty. The two groups were similar ($p > 0.1$) with respect to age at valvuloplasty, pulmonary anulus diameter, ratio of pulmonary artery to descending aorta diameter before valvuloplasty and interval to follow-up angiography. In contrast to patients in group B, patients in group A had a significant immediate improvement in systemic arterial oxygen saturation ($p < 0.01$) and a significant increase in pulmonary anulus diameter at follow-up angiography ($p < 0.001$). The growth of the branch pulmonary arteries was similar ($p > 0.1$) in the two groups.

Among 42 patients who have had surgical correction, a transannular patch for right ventricular outflow tract reconstruction was used in 27 (64%); there was no difference between groups A and B with respect to its use. Eight patients died (three after repair) and death could not be directly attributed to valvuloplasty in any.

Balloon valvuloplasty promotes growth of the pulmonary valve anulus and pulmonary arteries and is a useful alternative to an aortopulmonary shunt in patients with small pulmonary arteries or associated complex intracardiac defects.

(J Am Coll Cardiol 1990;18:159–65)

Balloon dilation of the pulmonary valve is now accepted as a safe and effective procedure for the relief of congenital pulmonary valve stenosis, both in infants and in older children (1–3). Although stenosis at the pulmonary valve level often forms an important component of the right ventricular outflow tract obstruction in tetralogy of Fallot, little has yet been reported (4,5) about the efficacy of balloon dilation of the pulmonary valve in this lesion. No long-term study of the effect of this procedure in relieving cyanosis or on subsequent growth of the pulmonary anulus and branch pulmonary arteries exists. This is in part due to the good results obtained with palliative aortopulmonary shunt procedures (6–9) and to the increased preference of some centers for primary correction of this lesion in infancy (10–12). However, shunt procedures are associated with a definite mortality rate and complications include shunt failure (8,9), distortion of the pulmonary arteries (13) and pulmonary hypertension (14).

Correction of tetralogy of Fallot in infants usually necessitates use of a transannular patch in the right ventricular outflow tract (10,11), which has been regarded as an additional risk factor for operative death (15). Placement of a transannular patch inevitably produces pulmonary regurgitation (16), and the long-term effects of this on the right ventricle are still unclear (16–19). In many centers, therefore, elective staged repair of the lesion is routinely performed with a good outcome (20).

Balloon pulmonary valvuloplasty is an alternative to aortopulmonary shunts for the relief of cyanosis. This report examines the effect of this procedure on relief of symptoms and on growth of the pulmonary anulus and branch pulmonary arteries.

Methods

Study patients. Over a 72 month period up to December 1989, balloon pulmonary valvuloplasty was attempted in 67 patients with a primary diagnosis of tetralogy of Fallot (58 patients), tetralogy of Fallot with a complete atrioventricular (AV) septal defect (7 patients), AV septal defect and aortic valve stenosis (1 patient) or a disconnected left pulmonary

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Manuscript received September 10, 1990; revised manuscript received December 6, 1990, accepted January 21, 1991.

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0735-1097/91/$3.50

artery and multiple aortopulmonary collateral arteries (1 patient). The patients ranged in age from 0.03 to 52 months (median 5) at the time of initial balloon dilation. The indications for the procedure were persistent central cyanosis or recurrent severe cyanotic spells; all were patients in whom intervention was considered necessary. In 65 patients, valvuloplasty was attempted as the primary palliative procedure; 2 patients had undergone a prior aortopulmonary shunt procedure without relief of symptoms. Informed consent from the parents was obtained before every procedure and the study protocol was approved by the hospital's Committee on Human Research.

Pulmonary valvuloplasty. All but six of the pulmonary valvuloplasty procedures were performed under general anesthesia. Parenteral morphine was routinely administered as premedication to lessen the probability of cyanotic spells during valvuloplasty. Propranolol was not given routinely during the procedure. A standard technique as described for dilation of stenotic pulmonary valves (2,3) was used. After right ventricular angiography, the maximal balloon size was chosen on the basis of the diameter of the pulmonary valve anulus (as measured from the hinge points of the leaflets in the anteroposterior projection) and the narrowest portion of the pulmonary artery outflow tract. A guide wire was positioned across the pulmonary valve by means of an end-hole catheter; the catheter was then withdrawn, leaving the guide wire in place. The balloon catheter was advanced over the guide wire and positioned so that the midpoint of the balloon was across the pulmonary valve anulus. The balloon was inflated with use of diluted contrast medium until the waist produced by the stenotic pulmonary valve was abolished and then was immediately deflated. When inflation of the balloon did not produce a waist, a larger balloon was used. The number of inflations performed during any procedure ranged from 1 to 10 (median 4). In most patients, arterial pressure was continuously monitored by a femoral artery catheter during the procedure and systemic arterial oxygen saturation was measured before and after the procedure.

Patients were retrospectively classified into one of three groups. In 35 patients, follow-up angiography had been performed at 3 to 30 months (median 12) after balloon dilation. Twenty-four (69%) of these patients (group A) either had not undergone another palliative procedure or had had adequate palliation with repeat valvuloplasty. The other 11 patients (31%) (group B) had required an aortopulmonary shunt at an interval of 0 to 3 months (median 1 month) after initial balloon dilation because of inadequate palliation. Thirty patients (group C) had not undergone repeat cardiac catheterization. The remaining two patients had had an aortopulmonary shunt inserted before balloon dilation and were excluded from statistical analyses.

Measurements. The maximal systolic diameter of the pulmonary anulus, of the right and left pulmonary arteries before the origin of their first branch at the hilum of the lung and of the descending aorta just above the level of the diaphragm at follow-up angiography was measured from each angiogram. To calculate the actual diameter of the pulmonary valve anulus, the ratio of the measured anulus diameter to the diameter of the angiographic catheter (measured at the junction of the inferior vena cava and right atrium) was corrected for the known external diameter of the catheter. The ratio of the combined diameters of the right and left pulmonary arteries to that of the descending aorta was also calculated (21). To account for changes in the diameter of the pulmonary valve anulus over time, the percent change in the anulus diameter during the follow-up period was compared with normal data for the pediatric age group (22).

Forty-two patients subsequently underwent total correction at 7 to 79 (median 33) months of age. In every case, the right ventricular outflow tract, pulmonary valve and main pulmonary artery were inspected for possible damage from the previous balloon valvuloplasty and these data are the subject of a separate report (23).

Statistical analysis. Data analysis was conducted with use of the Statistical Analysis System (SAS), version 5.18. Each variable received a test for normality of distribution before any calculations were made. Many but not all variables had a non-Gaussian distribution. For this reason, descriptive statistics for all variables are presented as median values, with range for consistency. Continuous variables were related with either an unpaired t test or a rank sum Wilcoxon test for intergroup comparison or a paired t test or sign rank Wilcoxon test for intragroup comparisons, as distribution of the data dictated. Tests of association were made by chi-square contingency analysis for categoric variables and the calculation of Pearson product moment or Spearman rho correlation coefficients for quantitative data.

Event-free actuarial analysis was made according to the method of Kaplan and Meier (24). Homogeneity of event-free rates was tested using the log-rank statistic. The elucidation of risk factors for requirement of a shunt and use of a transannular patch was made using stepwise multivariate logistic regression analysis.

Probability (p) values < 0.05 were regarded as significant, whereas those between 0.05 and 0.1 were considered to indicate a possibly significant relation. Probability values >0.1 were judged to be nonsignificant.

Results

Immediate results of the procedure. Overall, 86 balloon valvuloplasty procedures were attempted in 67 patients. The criterion for repeat balloon valvuloplasty was an increase in the degree of cyanosis at follow-up study, as assessed clinically after successful balloon valvuloplasty. The pulmonary valve could not be crossed at catheterization in three patients (including one patient in whom it could not be crossed at two separate catheterization procedures), and an aortopulmonary shunt was performed in all three. In two others whose pulmonary valve could not be crossed initially, balloon valvuloplasty was successfully performed at repeat

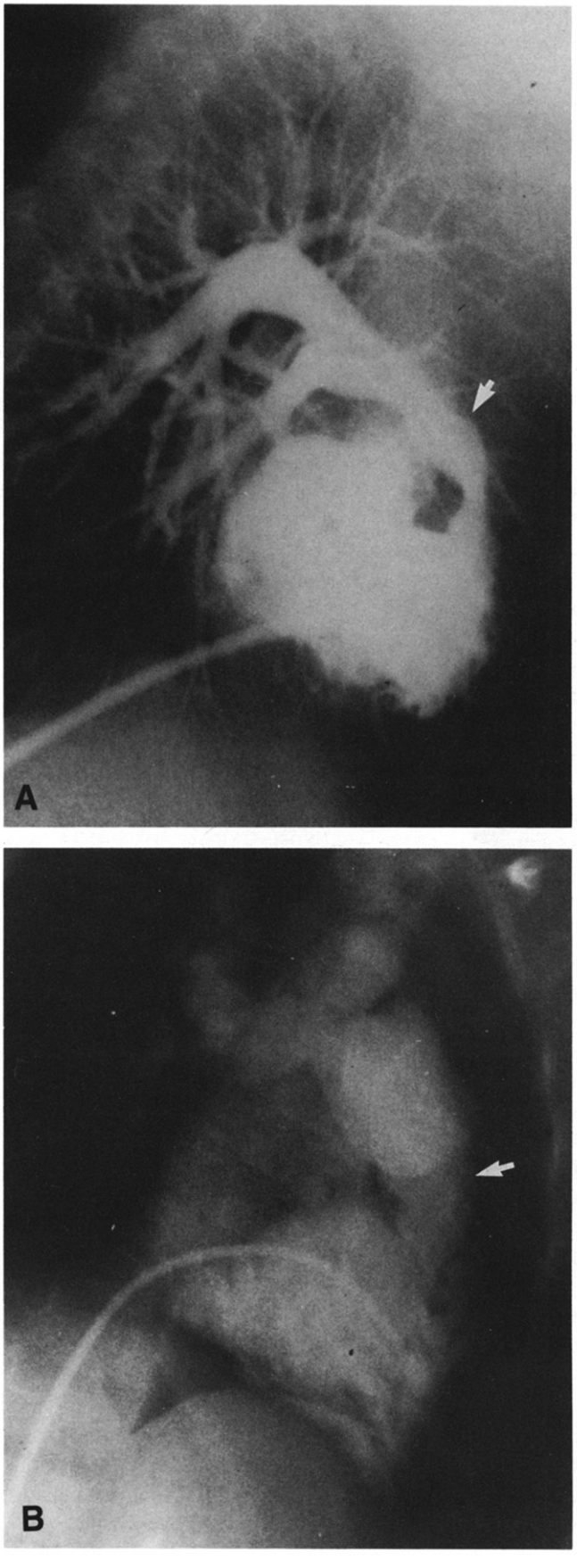
catheterization during the same hospital admission. The median screening time (as an indicator of the degree of radiation exposure) was 20 min (range 8 to 56) for patients aged <1 year and 25 min (range 6 to 62) for those >1 year.

The median duration of follow-up study was 27.5 months (range 0.66 to 63). For the entire study group, the median balloon/anulus ratio was 1.5 (range 0.9 to 3.4). Systemic arterial oxygen saturation immediately after balloon dilation increased from 74% (range 46% to 99%) to 90.5% (range 45% to 100%). Both the absolute difference between pre- and postdilation values and the percent change in systemic oxygen saturation (median 14.5, range −33.8 to +118.2) were highly significant ($p < 0.001$). Treatment with oral propranolol to prevent recurrent cyanotic spells was started 0 to 13 months (median 0.5 month) after balloon dilation in 17 (25%) of the 67 patients. Propranolol therapy was continued in the 11 patients who were receiving it before the procedure. In two patients, administration of propranolol was discontinued within 4 weeks after balloon valvuloplasty.

Group A: balloon valvuloplasty only, with follow-up angiography. Twenty-four patients had follow-up angiography 11 months (range 3 to 27) after balloon dilation. The median age at balloon dilation was 4 months (range 0.26 to 52) and median balloon/anulus ratio was 1.68 (range 0.99 to 2.83). Systemic oxygen saturation after initial balloon dilation improved from 74% (range 56% to 99%) to 91% (range 69% to 100%) ($p < 0.001$). Ten patients had required treatment with oral propranolol for episodic cyanosis; their pulmonary stenosis however, was considered to be adequately dilated. At follow-up angiography, the pulmonary valve anulus had increased in diameter from 6.8 mm (range 3.6 to 14) before dilation to 10.6 mm (range 6 to 26.8) ($p < 0.001$) (Fig. 1). The percent change in the pulmonary anulus diameter (median 55.1%, range −3.8% to 281.2%) was greater than that which might have been expected over the same duration of follow-up (median 19.5%, range 5.3% to 41.4%) as a function of growth alone ($p < 0.005$) (22). The ratio of the combined right and left pulmonary artery diameters to that of the descending aorta increased from 1.9 (range 0.6 to 3.4) to 2.2 (range 1.1 to 3.9) ($p < 0.001$). Seventeen of the 24 patients subsequently underwent surgical repair at a median age of 23 months (range 7 to 79), and there were no operative deaths.

On comparing the subset of 10 patients with a balloon/anulus ratio >1.5 (1.5 being the maximal recommended ratio [25,26] for dilation of isolated pulmonary valve stenosis) with the 10 who had a ratio <1.5, the valve anulus increased from 5.4 (range 3.6 to 8.4) to 9.2 mm (range 6 to 23.1) in the group with the larger balloon/anulus ratio versus a change from 8 (range 6.7 to 14) to 11.7 mm (range 7.5 to 26.8) in the patients with the smaller ratio. There was no significant difference in the absolute change in diameter between the two subsets of patients, although the percent change tended to be higher for those with the larger balloon/anulus ratio ($p < 0.1$).

Figure 1. Right ventricular angiograms in the same patient before (**A**) and 15 months after (**B**) balloon valvuloplasty, showing a clear increase in anulus diameter (**arrowheads**), which was significantly greater than that expected from growth alone.



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Group B: balloon valvuloplasty and aortopulmonary shunt with follow-up angiography. Eleven patients underwent an aortopulmonary shunt procedure 1 month (range 0 to 3 months) after the balloon dilation procedure because of persistent symptoms. Of these, four patients had also required oral propranolol for recurrent episodic cyanosis after balloon dilation. The median age at balloon dilation was 3 months (range 0.03 to 26) and balloon/anulus ratio was 1.6 (range 0.9 to 2.6). Systemic arterial oxygen saturation changed from 67% (range 47% to 83%) to 76% (range 45% to 97%) ($p > 0.1$). During a median follow-up period of 12 months (range 8 to 30), the pulmonary anulus diameter changed from 5.9 mm (range 3.4 to 9.3) before dilation to 9.7 mm (range 4.2 to 16.7) ($p < 0.01$). The percent change in pulmonary anulus diameter was 29.9% (range 8.1% to 183.1%) compared with the expected 29% (range 5.6% to 47.5%) due to growth alone ($p > 0.1$). The ratio of combined pulmonary artery diameters to descending aortic diameter increased from 1.7 (range 1.2 to 2.7) to 2.3 (range 1.6 to 3.2) ($p < 0.005$). Nine of the 11 patients had total correction at a median age of 39 months (range 25 to 52). There were two operative deaths.

Group A versus group B. *There were no significant differences between the two groups with respect to the following criteria:* 1) age at initial balloon dilation; 2) balloon/anulus ratio; 3) diameter of the anulus before balloon dilation; 4) ratio of the combined pulmonary artery diameters to descending aortic diameter before dilation or at follow-up angiography; and 5) interval between balloon dilation and follow-up angiography.

Patients in group B had significantly lower systemic arterial oxygen saturation before balloon dilation than did patients in group A ($p < 0.05$). Balloon dilation also produced a significantly greater increase in oxygen saturation in patients judged to have had an adequate palliative procedure (group A) and who did not require a subsequent aortopulmonary shunt ($p < 0.001$). However, no combination of variables before balloon dilation was able to significantly predict whether an individual patient would require an additional palliative procedure in the form of an aortopulmonary shunt. When systemic oxygen saturation after dilation was added to the analysis it emerged as the only variable associated with predicting the likelihood of a shunt ($p = 0.02$). Patients with a relatively low oxygen saturation after the balloon procedure had a greater probability of requiring a shunt than did those with a higher saturation. The interval between the balloon procedure and the next event (shunt, surgical correction or death) was also significantly reduced in group B patients ($p < 0.001$) (Fig. 2).

The median change in pulmonary anulus diameter was greater than that expected from growth alone in both groups (Fig. 3), but the difference in group B was very small. Thus, dilation alone (group A) produced an anulus 35.6% larger than that expected from growth alone, whereas dilation followed by a shunt procedure (group B) produced a change of only 0.9% greater than that predicted by growth.

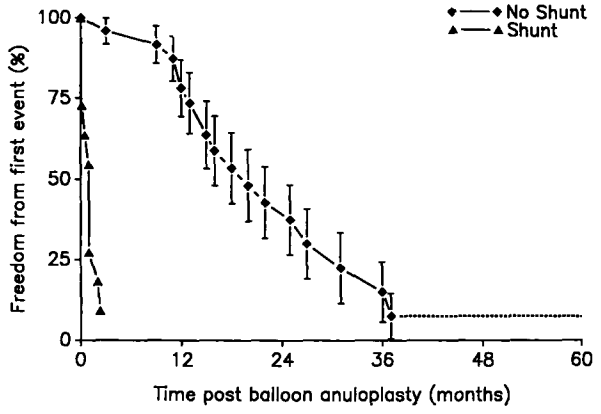
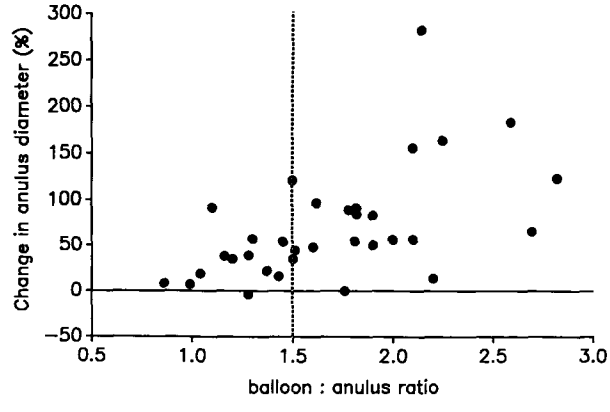


Figure 2. Graph showing the interval of freedom from the next event (shunt procedure, total repair or death) in group A (depicted as "no shunt") and group B ("shunt") after balloon valvuloplasty. Group B patients (n = 11) showed no significant improvement in systemic oxygen saturation after balloon dilation and had a median time to the next event (an aortopulmonary shunt) of 1 month. In contrast, group A patients (n = 24) had a significantly longer interval of freedom from the next event ($p < 0.001$).

For all group A patients, the balloon/anulus ratio correlated significantly with change in pulmonary anulus diameter ($r = 0.60$; $p < 0.001$) expressed as a percent of the predilation diameter. On considering the change in anulus diameter in the subgroups with a balloon/anulus ratio >2 or <2 the subjective impression was one of a smaller, yet more consistent increase in diameter in those with a ratio <2 and a greater but increasingly unpredictable and inconsistent change in diameter in those with a ratio >2 (Fig. 4). However, correlation coefficients for these subsets of data were nonsignificant. Overall, 14 patients required treatment with oral propranolol after initial balloon dilation. Four of these 14 subsequently underwent an aortopulmonary shunt, after which propranolol was stopped in all 4.

Figure 3. Scattergram of the balloon/anulus ratio (**x axis**) and the change in pulmonary anulus diameter (**y axis**) expressed as a percent of the original diameter. The percent change appears to be related to the balloon/anulus ratio up to a ratio of 2. The **dotted line** at 1.5 represents the recommended balloon/anulus ratio for dilation of isolated pulmonary stenosis (see text).



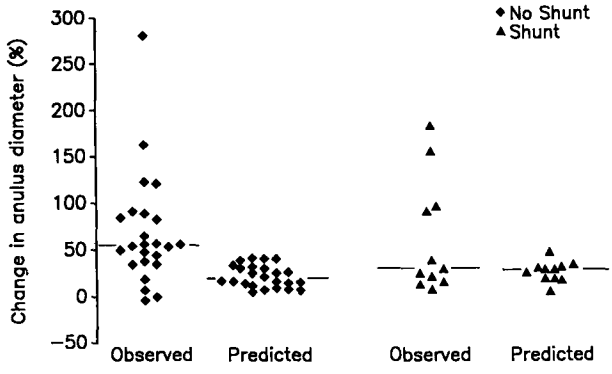


Figure 4. Scattergram of the observed and predicted changes in pulmonary anulus diameter for group A ("no shunt") and group B ("shunt") patients. Group A patients showed a significantly greater percent change in anulus diameter than expected from growth alone. In comparison, the change in group B patients is negligible.

Group C: balloon valvuloplasty only or balloon valvuloplasty and shunt, but no follow-up angiography. Thirty patients had not undergone another angiographic investigation after initial balloon dilation. Of these, three patients required treatment with oral propranolol after balloon valvuloplasty. During a follow-up period of 19.3 months (range 0.7 to 63), 7 patients required an aortopulmonary shunt; 16 patients had total correction 28.5 months (range 11 to 57) after balloon valvuloplasty (1 of the 16 died at operation). Five other patients died during the follow-up period (see Mortality); the remaining two patients are in stable condition and awaiting corrective surgery.

Complications. There were no deaths during or immediately after balloon valvuloplasty. A transient increase in cyanosis was seen during the procedure, and two patients received intravenous propranolol. Two patients who had no improvement in oxygen saturation received an aortopulmonary shunt during the same hospital admission. One patient developed transient pulmonary edema several hours after the procedure and required temporary mechanical ventilation. One patient developed group D streptococcal septicemia after catheterization and required intravenous antibiotic therapy. Two patients (both with a balloon/anulus ratio >2.5) developed cardiac tamponade and underwent emergency surgical repair of the right ventricular outflow tract, followed by insertion of an aortopulmonary shunt in one patient. The incidence of these major and minor complications was similar to that reported (27) for other large series of catheter interventional procedures.

Deaths. Overall, 8 (12%) of the 67 patients died during the follow-up period. There were three postoperative deaths associated with a low cardiac output. One patient in group B whose pulmonary valve could not be crossed at cardiac catheterization on two separate occasions died at home because of shunt failure 21 months after a shunt procedure. One patient who developed bacterial septicemia after balloon dilation died at home 14 months later and at autopsy healed vegetations were seen on the tricuspid valve. Three other patients died 5 days, 5 months and 7 months, respectively, after balloon dilation. The first of these patients had tetralogy of Fallot with a complete AV septal defect and severe aortic valve stenosis and died suddenly in the hospital. The other two patients had multiple congenital abnormalities (velocardiofacial syndrome in one [velopharyngeal insufficiency, cleft palate, learning difficulties and a characteristic facies] and VATER syndrome [a combination of vertebral, anal, tracheoesophageal, radial and renal anomalies] with a complete AV septal defect in the other). At autopsy there was no evident damage to the right ventricular outflow tract as a result of previous balloon valvuloplasty.

Corrective surgery. Forty-two patients have undergone total correction during the follow-up period. There were three early deaths (including one in a patient with an associated complete AV septal defect). Twenty-seven patients (64%) required transannular patch reconstruction of the right ventricular outflow tract, including six of the nine patients from group B who had had a palliative shunt and the two patients who had undergone an aortopulmonary shunt procedure before balloon dilation. Thus, there was no difference in the requirement for a transannular patch between patients adequately treated by balloon dilation and those requiring a shunt. On logistic regression analysis, three variables were identified as potentially important predictors of the need for a transannular patch at subsequent repair. These were 1) a smaller anulus size at follow-up angiography ($p = 0.07$); 2) a lower pulmonary artery/aorta diameter ratio ($p = 0.1$); and 3) a higher balloon/anulus ratio at valvuloplasty ($p = 0.08$).

Discussion

Balloon dilation is now accepted as a safe and effective method for the treatment of congenital pulmonary stenosis (1–3). Stenosis at the pulmonary valve level is often an important cause of right ventricular outflow obstruction in tetralogy of Fallot, and balloon pulmonary valvuloplasty was performed as an alternative to an aortopulmonary shunt in patients who were believed to merit intervention on clinical grounds. The large variation in the balloon size (and therefore the balloon/anulus ratio) was due in part to the limited number of balloon sizes available for use in the early part of this experience and to the inaccuracy in measuring the anulus diameter at catheterization.

Group A and group B. Preliminary results of balloon valvuloplasty reported from this institution (4) suggested an immediate improvement in systemic arterial oxygen saturation, a shorter hospital stay and avoidance of a shunt procedure. Although patients were not randomized before initial intervention to directly compare the results of balloon dilation and a shunt procedure, two such groups became available for comparison because some patients in whom balloon valvuloplasty failed to produce sustained clinical improvement received an aortopulmonary shunt. In those patients who required a palliative shunt (group B), the

interval between balloon valvuloplasty and the shunt procedure was also sufficiently short (Fig. 2) that changes seen at follow-up angiography may be reasonably attributed to the effects of the shunt.

Changes in pulmonary anulus diameter. Ideally, any comparisons of changes in pulmonary anulus diameter at follow-up angiography should be made against serial angiographic data on unoperated patients with tetralogy of Fallot. However, this was not possible because all patients in this series were symptomatic and required intervention. The change in pulmonary anulus diameter during the follow-up period was therefore compared with that expected from growth alone, using data obtained from postmortem examination of children who had died from noncardiac events (22). Because of difficulties in making quantitative comparisons between formalin-fixed postmortem specimens and their equivalents in life, changes in the pulmonary anulus between initial balloon valvuloplasty and follow-up angiography were expressed as a percent of the original anulus diameter. The better technical result in the patients not requiring a shunt procedure (group A), as evidenced by a significant elevation in oxygen saturation immediately after dilation, was perpetuated at follow-up angiography in an anulus much larger than could be achieved by growth alone. After a shunt procedure, the anulus diameter did increase to a size just larger than expected, but the change was negligible compared with a technically satisfactory balloon dilation. Growth of the pulmonary arteries, expressed as the ratio of the combined pulmonary artery diameters to that of the descending aorta, was comparable in the two groups, reflecting the increase in pulmonary blood flow produced by a technically satisfactory balloon dilation or shunt procedure.

Primary repair in infancy versus staged correction. Primary total correction of tetralogy of Fallot in infancy is now being performed in some centers (10,11), with an acceptable operative mortality rate. Although the early results after correction in infants have been encouraging, there are limited long-term follow-up studies (16) of the hemodynamic and functional status. Correction in infants usually involves the placement of a transannular patch in the right ventricular outflow tract. In the earlier surgical series (15), this was an additional risk factor for total correction in infancy, although more recent experience (10,11) does not suggest a higher operative mortality rate. Insertion of a transannular patch inevitably produces pulmonary regurgitation. In the largest reported series of primary repair in infancy (16), pulmonary valve incompetence was present in 89% of patients with a transannular patch or nonvalved right ventricle to pulmonary artery conduit. Although none of these patients had required pulmonary valve replacement during a mean follow-up period of 60 months, 18% of these patients had at least a moderate degree of cardiomegaly on a late chest X-ray study, presumably related to chronic pulmonary insufficiency. Although pulmonary regurgitation appears to be well tolerated clinically in the short or medium term, several studies (17–19) have illustrated its long-term deleterious effect on right ventricular performance.

Staged surgical repair therefore continues to be used as an alternative to primary correction, particularly in patients with a small pulmonary anulus and pulmonary arteries and other associated risk factors such as a complete AV septal defect. Although an aortopulmonary shunt can be inserted with a low mortality rate and may reduce the necessity for a transannular patch, there is a small but definite incidence of shunt failure requiring reoperation (8) and of complications such as distortion of the pulmonary arteries or pulmonary hypertension (13,14). In some of these patients, balloon dilation of the pulmonary valve may be a suitable alternative to an aortopulmonary shunt.

In retrospect, however, it was not possible to predict before intervention which patients might benefit maximally from balloon dilation. This observation may reflect the wide morphologic variability of the right ventricular outflow tract, pulmonary valve and pulmonary arteries in patients with tetralogy of Fallot.

Role of infundibular stenosis. Even when it was effective in relieving obstruction at the valve level and diminishing cyanosis, balloon valvuloplasty did not always prevent subsequent cyanotic spells, although these were well controlled with oral propranolol. Such spells may be attributed to dynamic infundibular stenosis. However, infundibular stenosis was very difficult to quantify and assessment of its severity in terms of the length of the infundibular septum, its thickness in systole or the minimal systolic diameter of the right ventricular outflow tract did not correlate with the clinical status after balloon valvuloplasty.

Although a significant proportion of patients required a transannular patch at surgical correction, there was no difference between patients who had required a shunt and those who had undergone palliation by balloon dilation alone for this event. For both groups, the use of a transannular patch was associated with a smaller valve anulus and pulmonary arteries.

Mortality. Of the eight deaths in the series, only one (in the patient with vegetations on the tricuspid valve at autopsy) might be attributed to the effects of balloon dilation, although this death was a late event (14 months later). None of the three operative deaths were related to the effects of previous balloon dilation. In the unoperated patients, two had multiple congenital anomalies and in two there was a complete AV septal defect in addition to tetralogy of Fallot.

Conclusions. Balloon dilation of the pulmonary valve is a relatively safe procedure and appears to produce adequate palliation in most patients with tetralogy of Fallot, while promoting growth of the pulmonary anulus and branch pulmonary arteries. In view of the possible damaging effects of large balloons and the less consistent relation between changes in anulus diameter and a larger balloon/anulus ratio, the maximal balloon/anulus ratio should not be >2. Finally, balloon pulmonary valvuloplasty is a useful alternative to an aortopulmonary shunt and may allow later total correction in

some patients with poorly developed pulmonary arteries or with associated complex intracardiac defects. Failure to achieve an immediate increase in systemic arterial oxygen saturation of ≥10% over the prevalvuloplasty level may be an indication for an aortopulmonary shunt.

We thank Jean Beamer and Christine Daniels for their assistance in retrieving the data.

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